UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ACELLA PHARMACEUTICALS, LLC,

Plaintiff,

v.

ANI PHARMACEUTICALS, INC.,

Defendant.

ANI PHARMACEUTICALS, INC.,

Counterclaim Plaintiff,

v.

ACELLA PHARMACEUTICALS, LLC,

Counterclaim Defendant.

Case No.: 0:24-cv-00774 (DSD/TNL)

ANI PHARMACEUTICALS, INC.'S ANSWER AND COUNTERCLAIMS

For their answer under Federal Rule of Civil Procedure 8(b) to Plaintiff and Counterclaim Defendant Acella Pharmaceuticals, LLC's ("Acella") Complaint, Defendant and Counterclaim Plaintiff ANI Pharmaceuticals, Inc. ("ANI", "Defendant" or "Counterclaim Plaintiff") states as follows:

1. ANI admits this case concerns Acella's prescription-only natural desiccated thyroid (NDT) therapy, NP Thyroid® (thyroid tablets, USP), and ANI's prescription-only Thyroid Tablets. ANI denies that it is the result of NP Thyroid®'s

quality that NP Thyroid® is a leading NDT thyroid treatment option in the U.S. and ANI is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 1, and therefore denies them.

2. ANI admits that it markets 30 mg, 60 mg, and 90 mg dosages of thyroid tablets, the labels for those dosages state "Thyroid Tablets USP", and that ANI's Thyroid Tablets satisfy USP's quality standards. ANI denies the remaining allegations in paragraph 2.

3. ANI denies the allegations in paragraph 3.

4. The allegations in paragraph 4 include legal conclusions to which no response is required. ANI admits that Acella brings this action under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Minnesota state law. ANI admits that its Thyroid Tablets are not an FDA approved generic to NP Thyroid. ANI denies it has caused injury to Acella, that Acella is entitled to any relief and ANI denies the remaining allegations in paragraph 4.

5. ANI admits that Acella is a limited liability company formed under the laws of the State of Delaware, with its principal place of business in Alpharetta, Georgia but is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 5 and therefore denies them.

6. ANI admits that it is a publicly-traded corporation organized under the laws of Delaware, with its principal place of business at 210 Main Street West, Baudette, Minnesota 56623. ANI admits that it markets its Thyroid Tablets in

Minnesota and throughout the United States and denies the remaining allegations in paragraph 6.

7. ANI admits the allegations in paragraph 7.

8. ANI admits that venue is proper in this district under 28 U.S.C. § 1391(b).

9. ANI admits that this Court has personal jurisdiction over it and that ANI offers for sale and sells Thyroid Tablets throughout the United States, including in the District of Minnesota. ANI denies that Acella has been harmed by ANI's conduct and denies the remaining allegations in paragraph 9.

10. ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 10 and therefore denies them.

11. ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 11 and therefore denies them.

12. ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 12 and therefore denies them.

13. ANI admits that the FDA has acted on non-compliant DTE products, such as Acella's NP Thyroid®, for failing to meet their label and USP claims. ANI admits that the link in paragraph 13 is to a consumer update on the FDA's website, which is an article entitled "Older Therapies Aren't Necessarily Better for Thyroid Hormone Replacement" which states that "Manufacturing DTE from pig glands tends to be a more complex process, and may result in safety, effectiveness, and quality

issues because of inconsistent and inaccurate doses." ANI is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 13 and therefore denies them.

14. ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 14 and therefore denies them.

15. ANI admits that the link in paragraph 15 is to a February 5, 2024 Warning Letter to Sichuan Deebio Pharmaceutical Co., Ltd.. ANI is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 15 and therefore denies them.

16. ANI admits that Acella purports to have launched NP Thyroid® in 2010 and denies the remaining allegations of paragraph 16.

17. ANI admits that Acella purports to offer NP Thyroid® in 30 mg, 60 mg, and 90 mg dosages with the below labels. ANI is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 17 and therefore denies them.

18. ANI admits that it describes itself as "an integrated specialty pharmaceutical company," and markets both generic and brand products. ANI admits in 2023 that it launched its Thyroid Tablets in 30 mg, 60 mg, and 90 mg dosages as a DTE treatment and that the labels included in paragraph 18 purport to be portions of ANI's Thyroid Tablet labels. ANI denies the remaining allegations in paragraph 18.

19. ANI admits that it marks its labels with "USP." To the extent the

allegations in paragraph 19 consist of legal conclusions no response is required. To the extent a response is required, ANI denies the remaining allegations in paragraph 19.

20. The allegations in paragraph 20 consist of legal conclusions to which no response is required. To the extent a response is required, ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 20 and therefore denies them.

21. ANI admits that the USP includes a USP monograph for Thyroid Tablets. The remaining allegations consist of a legal conclusion to which no response is required. To the extent a response is required, ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 21 and therefore denies them.

22. ANI admits that patients taking NP Thyroid® or ANI's Thyroid Tablets must first obtain a prescription from their doctors, and then obtain their thyroid tablet product through a pharmacy (either retail or on-line). ANI admits that it does not have a registered trademark for the name of its thyroid products. ANI denies that all doctors only write prescriptions for brand name thyroid tablets. ANI denies the remaining allegations in paragraph 22.

23. ANI admits that products are considered to be pharmaceutical equivalents if they contain the same ingredient(s) and the same active ingredient(s), are of the same dosage form and route of administration and contain identical in

strength or concentration. To the extent the allegations in paragraph 23 consist of legal conclusions no response is required. To the extent a response is required, ANI denies the remaining allegations in paragraph 23.

24. ANI denies the allegations of paragraph 24.

25. ANI admits that it listed its Thyroid Tablet products with drug pricing databases including Medi-Span® (a Wolters Kluwer company) and First DataBank (a Hearst Health company). ANI admits that it sells Thyroid Tablet products through wholesalers and drug retailers. ANI denies the remaining allegations of paragraph 25.

26. ANI admits that drug information databases link pharmaceutically equivalent products to one another. ANI admits that linking is a data point pharmaceutical wholesalers, retail pharmacy chains, and others in the pharmaceutical supply chain use to determine substitution.

27. ANI admits that its Thyroid Tablets are lower-cost than Acella's NP Thyroid®. ANI denies the remaining allegations of paragraph 27.

28. ANI denies the allegations of paragraph 28.

29. ANI admits that it has a link to GoodRx on its website. ANI denies the remaining allegations in paragraph 29.

30. ANI admits that GoodRx lists ANI's Thyroid tablets as a lower-cost alternative to NP Thyroid®. ANI denies the remaining allegations in paragraph 30.

31. ANI denies the allegations in paragraph 31.

32. ANI admits that its Form 10-K (Mar. 9, 2023) speaks for itself. ANI is

without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 32 and therefore denies them.

33. ANI is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 33 and therefore denies them.

34. ANI denies the allegations in paragraph 34.

35. ANI denies the allegations in paragraph 35.

36. ANI denies the allegations of paragraph 36.

37. ANI denies the allegations of paragraph 37.

38. ANI denies the allegations of paragraph 38.

COUNT I
FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT, 15 U.S.C. § 1125(a)

39. ANI restates and incorporates by reference the responses set forth in the paragraphs above.

40. ANI denies the allegations of paragraph 40.

41. ANI denies the allegations of paragraph 41.

42. ANI denies the allegations of paragraph 42.

43. ANI denies the allegations of paragraph 43.

44. ANI denies the allegations of paragraph 44.

45. ANI denies the allegations of paragraph 45.

COUNT II
VIOLATION OF THE MINNESOTA UNFAIR TRADE PRACTICES ACT, MINN. STAT. § 325D.13

46. ANI restates and incorporates by reference the responses set forth in the paragraphs above.

47. The allegations in paragraph 47 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the remaining allegations in paragraph 47.

48. The allegations in paragraph 48 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the remaining allegations in paragraph 48.

49. ANI denies the allegations of paragraph 49.

50. ANI denies the allegations of paragraph 50.

51. ANI denies the allegations of paragraph 51.

52. ANI denies the allegations of paragraph 52.

53. ANI denies the allegations of paragraph 53.

COUNT III
VIOLATION OF THE MINNESOTA UNIFORM DECEPTIVE TRADE PRACTICES ACT, MINN. STAT. § 325D.44

54. ANI restates and incorporates by reference the responses set forth in the paragraphs above.

55. The allegations in paragraph 55 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the

remaining allegations in paragraph 55.

56. The allegations in paragraph 56 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the remaining allegations in paragraph 56.

57. ANI denies the allegations of paragraph 57.

58. ANI denies the allegations of paragraph 58.

59. ANI denies the allegations of paragraph 59.

60. ANI denies the allegations of paragraph 60.

COUNT IV
VIOLATION OF THE MINNESOTA FALSE ADVERTISING ACT MINN. STAT. § 325F.67

61. ANI restates and incorporates by reference the responses set forth in the paragraphs above.

62. The allegations in paragraph 62 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the remaining allegations in paragraph 62.

63. The allegations in paragraph 63 consist of legal conclusions to which no response is required. ANI denies that Acella is entitled to any relief and denies the remaining allegations in paragraph 63.

64. ANI denies the allegations of paragraph 64.

65. ANI denies the allegations of paragraph 65.

66. ANI denies the allegations of paragraph 66.

JURY DEMAND

ANI admits that Acella demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

ANI denies that Acella is entitled to any relief and denies any remaining allegations in the Prayer for Relief.

ANI denies any remaining allegation in Acella's Complaint that has not previously been addressed in this Answer.

AFFIRMATIVE DEFENSES

Further responding to Acella's Complaint and as additional defenses thereto, ANI asserts the following affirmative defenses, without admitting any allegations of the Complaint not previously admitted.

FIRST AFFIRMATIVE DEFENSE
(Unclean Hands)

1. Acella's request for relief is barred by the equitable doctrine of unclean hands because Acella has made demonstrably false statements, misrepresentations, and misstatements of law about ANI's Thyroid Tablets and Acella's NP Thyroid® product, including material statements relating to NP Thyroid®'s approval status, cost, medical necessity, and quality, to ANI's potential and existing customers and caused ANI to lose both sales of its Thyroid Tablets and customers.

SECOND AFFIRMATIVE DEFENSE
(Preclusion and Preemption)

2. Acella's request for relief is barred because ANI's claims are precluded and preempted by federal law, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

THIRD AFFIRMATIVE DEFENSE
(Failure to Mitigate)

3. Acella's request for relief is barred because it has failed to mitigate its damages, if any, and is therefore not entitled to recover any damages.

RESERVED DEFENSES

ANI reserves all affirmative defenses under Federal Rule of Civil Procedure 8(c), the Lanham Act, the Minnesota Unfair Trade Practices Act, the Minnesota Uniform Deceptive Trade Practices Act, the Minnesota False Advertising Act Minnesota common law, and any other defenses, at law or equity, which may now exist or in the future may be available based on discovery and further factual investigation in this case.

COUNTERCLAIMS

PARTIES

1. Counterclaim Plaintiff ANI Pharmaceuticals, Inc. ("ANI") is a corporation organized under the laws of Delaware and has its principal place of business at 210 Main Street West, Baudette, Minnesota 56623. ANI markets Thyroid Tablets in Minnesota and throughout the United States.

2. Acella Pharmaceuticals, LLC ("Acella") is a limited liability company formed under the laws of the State of Delaware, with its principal place of business in Alpharetta, Georgia. Acella markets NP Thyroid® Tablets in Minnesota and throughout the United States.

JURISDICTION AND VENUE

3. ANI brings this action under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and this Court has original subject matter jurisdiction over ANI's Counterclaims under 28 U.S.C. §§ 1331 (federal question), 1367 (supplemental jurisdiction), 1338 (unfair competition), 2201 (declaratory judgment), and 15 U.S.C. §§ 1116 & 1121 (providing this Court original jurisdiction over Lanham Act claims and claims for injunctive relief under the Lanham Act).

4. Venue is proper in this judicial district for these Counterclaims under 28 U.S.C. § 1391.

5. The exercise of personal jurisdiction in Minnesota is proper because Acella purposely availed itself to this district by bringing this suit, because ANI's Counterclaims are related to Acella's claims, and because Acella markets, promotes, advertises, offers for sale, sells, and/or distributes its NP Thyroid® Tablets to customers, including drug wholesalers, pharmacies, and others, throughout the United States, including in the District of Minnesota.

SUMMARY OF CLAIMS

6. This lawsuit involves direct head-to-head competition for non-FDA-approved prescription natural desiccated thyroid tablets ("DTE" or "NDT" tablets) that are sold by both ANI and Acella in numerous dosages (respectively, "ANI's Thyroid Tablets" and "Acella's NP Thyroid® Tablets"). ANI has invested a significant amount of time, effort and expense into the development and manufacture of its substantially lower-cost Thyroid Tablets.

7. However, through Acella's large sales force and website, Acella falsely and misleadingly advertises to doctors, patients, pharmacies, insurance companies, drug databases, wholesalers and others in the market, that (1) ANI's Thyroid Tablets are an inferior or non-permissible substitute for Acella's NP Thyroid® Tablets and (2) further that Acella's NP Thyroid Tablets are the "generic" equivalent to Armour® Thyroid, a leading DTE brand. Through this activity Acella has inhibited the uptake of ANI's Thyroid Tablets over the course of their launch and harmed the sales of ANI's Thyroid Tablets.

8. This campaign is false and misleading, because ANI's Thyroid Tablets are a substitutable alternative for Acella's NP Thyroid® Tablets (and Armour® Thyroid) and because Acella's NP Thyroid Tablets are not the generic for Armour® Thyroid, but rather are "pharmaceutically equivalent" to ANI's Thyroid Tablets as alternative DTE products, except that ANI's Thyroid Tablets are lower-cost alternative than NP Thyroid® Tablets.

9. Because ANI's Thyroid Tablets are a lower-cost DTE alternative to Acella's NP Thyroid®, ANI's Thyroid Tablets should have captured significant market share upon their initial entry into the market and maintained that market share for prescriptions written for DTE tablets. ANI's Thyroid Tablets provide significant cost savings over Acella's NP Thyroid® under normal, competitive market conditions.

The Parties' Products

10. ANI's Thyroid Tablets contain the same active ingredients in the same strengths and the same dosage form, and have the same route of administration, as Acella's NP Thyroid® Tablets, making ANI's and Acella's products "pharmaceutically equivalent".

11. Acella's NP Thyroid® Tablets, like ANI's Thyroid Tablets, are not listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, known commonly as the "Orange Book."

12. The Orange Book contains drugs approved by the FDA and their approved generic interchangeable equivalents.

13. Because Acella's NP Thyroid® Tablets and ANI's Thyroid Tablets are not listed in the Orange Book, they are not FDA approved generics or brands, and they are not FDA "A-rated" equivalents to one another, and neither can be said to be "A-rated" to any other DTE tablet including Armour® Thyroid.

14. On information and belief, pharmacists generally rely on their pharmacies' prescription dispensing software when deciding whether to substitute drugs for those prescribed by physicians.

Medi-Span and First Databank

15. To market drug products, manufacturers provide information about the active ingredients in those products and pricing to third-party drug pricing databases Medi-Span and First Databank, which are available only by subscription.

16. Listings on Medi-Span and First Databank are necessary to market and promote drug products, in part because unlisted drugs will not be covered by insurance companies.

17. Medi-Span and First Databank use the listing of active ingredients and strengths on drug products' labels to group pharmaceutically equivalent products. Other industry participants, such as pharmacists, in turn rely on Medi-Span and First Databank to group pharmaceutically equivalent products in their prescription management software.

18. When making the decisions to substitute drugs for those prescribed by physicians, pharmacists rely on their pharmacies' prescription management software specifically, drug formularies, and others in the healthcare industry generally, to make decisions about substitution.

ANI's Listings

19. ANI listed its Thyroid Tablets with the U.S. Food and Drug Administration, the National Library of Medicine DailyMed website, and third-party drug pricing databases Medi-Span and First Databank to provide information to the market regarding pricing and availability of ANI's Thyroid Tablets.

20. The Medi-Span listing in Acella's Complaint showing ANI's Thyroid Tablets and Acella's NP Thyroid® Tablets indicates in the "therapeutic equivalence evaluation" ("TEE") field that the products are "NR" (not rated) indicating that the FDA has not rated the products as therapeutically equivalent to any other product.

NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Description	Labeler Name	Labeler Code
62559-0742-01	Thyroid Oral Tablet 60 MG	100 EA		1 Bottle		ANI PHARMACEUTICALS	62559

GPI Cross Reference - Thyroid Tab 60 MG (1 Grain) (28-10-00-50-00-03-15) - Package Size 100

NDC/UPC/HRI	Product Name	AWP	DP	WAC	ACA FUL	AAWP	GEAP	AWAC	GEWAC	Labeler	MS	TEE	Rx
00456-0459-01	Armour Thyroid Oral Tablet 60 MG	$128.33	$106.94	$106.94		$0.00		$0.00		ALLERGAN	N	NR	R
42192-0330-01	NP Thyroid Oral Tablet 60 MG	$116.11		$76.39		$0.00		$0.00		ACELLA PHARMACEUTICALS	N	NR	R
50090-0190-00	Armour Thyroid Oral Tablet 60 MG	$110.86								A-S MEDICATION SOLUTIONS	N	NR	R
62559-0742-01	Thyroid Oral Tablet 60 MG	$110.58		$69.11		$0.00		$0.00		ANI PHARMACEUTICALS	N	NR	R

21. The Medi-Span listing additionally demonstrates that the wholesale acquisition cost ("WAC") and average wholesale price ("AWP") for ANI's Thyroid Tablets are lower than Acella's NP Thyroid® Tablets.

Acella's History of FDA Violations

22. Acella has a long history of FDA violations with respect to NP Thyroid® Tablets. Upon information and belief, these violations continue to this day.

23. In 2020, Acella began recalling lots of its NP Thyroid® Tablets because the FDA found that Acella's NP Thyroid® Tablets were "adulterated". As a result of this finding, the FDA issued a Warning Letter to Acella finding "significant violations

of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals." Exhibit 1 at p. 1.[1] The Warning Letter summarizes significant violations of CGMP regulations by Acella and found that Acella's NP Thyroid® products were "adulterated" for their failure to conform to compendial standards for strength, quality, or purity and because Acella's "methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP" under the FD&C Act, 21 U.S.C. 351(b) and 21 U.S.C. 351(a)(2)(B). Id. at p. 1.

24. The FDA further found that Acella did not have long-term stability data to support the batches it had manufactured, which is "critical for ensuring that products maintain their identity, strength, quality, purity, and safety throughout their labeled shelf-lives." Id. at p. 2.

25. Acella's quality control issues did not begin or end in 2020; they go back to at least 2012 and appear to be ongoing. From March 19–22, 2012, through 2023, the FDA has conducted Good Manufacturing Practices ("GMP") inspections of Acella and noted several concerns on numerous occasions. Further, FDA has identified hundreds of adverse event complaints for NP Thyroid® Tablets collectively, which were deemed serious enough by the complainants to require an emergency room or primary care practice patient visit, the need to halt self-administration of Acella's NP Thyroid®

[1] Exhibit 1, August 14, 2020, FDA Warning Letter to Acella ("Acella Warning Letter"), (also accessible at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/acella-pharmaceuticals-llc-604438-08142020).

medication, and/or a reversion by the patient to an alternative therapy to halt the often-debilitating side effects of NP Thyroid®, which Acella had improperly classified as nonserious so as not to report those events to the FDA. See e.g., Exhibit 2 at p 22.

26. The FDA's website also indicates that at Acella's most recent inspection, ending February 20, 2023, Acella still has unresolved issues with its quality control unit and laboratory controls including the scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identify, strength, quality, and purity.[2]

FEI Number	Firm Name	Firm Address
3006691461	Acella Pharmaceuticals, LLC	1880 Mcfarland Pkwy Ste 110

Back to Top | FDA Actions Timeline | Inspections | Compliance Actions | Recalls | Import Refusals | Import Alerts | Warning Letters

Inspection ID	Inspection End Date	Program Area	Act/CFR Number	Short Description	Long Description
1197977	02/10/2023	Drugs	21 CFR 211.22(c)	Approve or reject procedures or specs	The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.
1197977	02/10/2023	Drugs	21 CFR 211.160(b)	Scientifically sound laboratory controls	Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.
1197977	02/10/2023	Drugs	21 CFR 211.192	Investigations of discrepancies, failures	There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.
1197977	02/10/2023	Drugs	21 CFR 211.198(a)	Procedures to be written and followed	Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

27. Based upon this history, which is well known to customers in the industry, customers were and are eager for an additional, reliable supplier of DTE tablets. However, upon information and belief, Acella's unfairly competitive actions described

[2] See https://datadashboard.fda.gov/ora/firmprofile.htm?FEIs=3006691461&/identity/3006691461.

below have inhibited ANI's ability to capture market share for its substantially lower-cost Thyroid Tablets.

Acella's False Representations and Unfair Competition

28. Upon information and belief, Acella uses a large, dedicated sales force to falsely and misleadingly promote its NP Thyroid® Tablets to doctors, insurance formularies, wholesalers, pharmacies, third-party websites, and to others throughout the healthcare industry as the "generic" equivalent to Armour® Thyroid. Acella further falsely and misleadingly advertises to those participants that ANI's Thyroid Tablets are not a permissible substitute for Acella's NP Thyroid® Tablets and that Acella's NP Thyroid® Tablets are of superior quality to ANI's Thyroid tablets.

29. Acella reinforces this false and misleading claim that its NP Thyroid® Tablets are a superior treatment to other desiccated thyroid tablet products, including ANI's Thyroid Tablets, without any evidence to support that claim, through its website for NP Thyroid® by misleading the market as to the quality and cost of NP Thyroid® Tablets.

30. To mislead the market into believing that ANI's Thyroid Tablets are not a permissible substitute for Acella's product and that NP Thyroid® Tablets are the generic for Armour® Thyroid, Acella falsely advertises that NP Thyroid® Tablets are of higher quality than ANI's Thyroid Tablets, are low cost and medically necessary to dispense, and have better insurance reimbursement coverage than other DTE tablets. Acella additionally misleads patients and providers into believing that due to Acella's

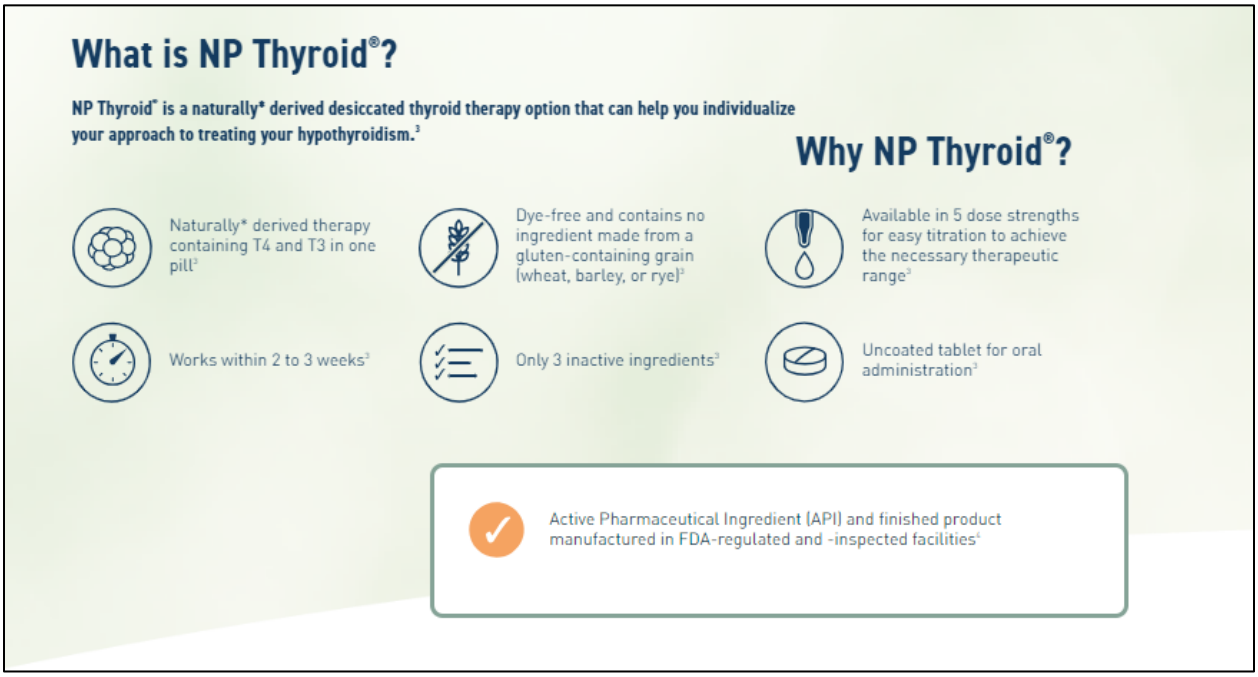
quality and by virtue of Acella manufacturing NP Thyroid® Tablets in FDA regulated and inspected facilities, that patients should request that doctors write prescriptions as "dispense as written" or "brand medically necessary", and that doctors should write "dispense as written" or "brand medically necessary" when Acella has no valid or FDA approved scientific basis to support any claim that its NP Thyroid® Tablets are higher quality or better than other DTE tablets such as ANI's Thyroid Tablets.

31. Acella has relied on its anti-competitive marketing strategy to maintain its market share despite numerous price hikes for its NP Thyroid® Tablets over the years and the entry of ANI's lower-cost Thyroid Tablets, directly harming ANI and its sales of its Thyroid Tablets. Acella revealed this marketing strategy in its Izeen action, stating that its success in linking its drug to Armour® Thyroid enabled Acella "to raise its prices in step with Armour without losing share." Exhibit 3 at p. 6 of Cook Report.

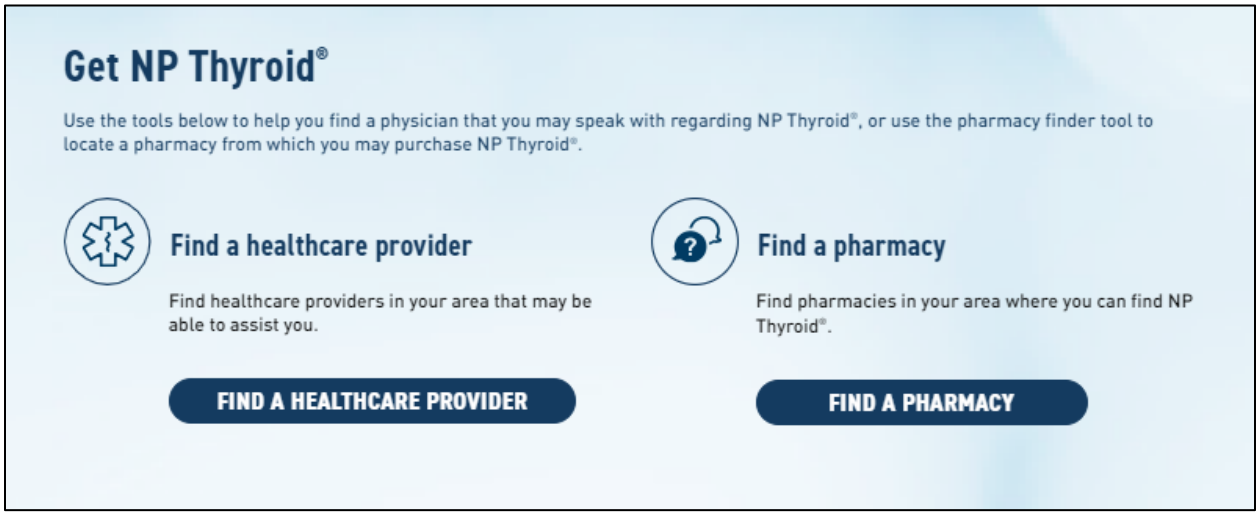
32. Acella misrepresents the quality of its NP Thyroid® Tablets through its NP Thyroid® webpage. Acella advertises that its products are "Produced and Manufactured in a Way You Can Feel Good About." Along with this statement, Acella implies to consumers, doctors and other healthcare providers, and the pharmaceutical industry that they can feel good about the way NP Thyroid® Tablets are produced and manufactured because their "Active Pharmaceutical Ingredient (API) and finished product [are] manufactured in FDA-regulated and inspected facilities" yet Acella misleadingly fails to inform doctors and consumers concerning the numerous negative findings by the FDA during inspections of those facilities and in the FDA issued

Warning Letter to Acella because they would not "feel good" about those negative findings. Exhibit 4, also available at https://npthyroid.com/.

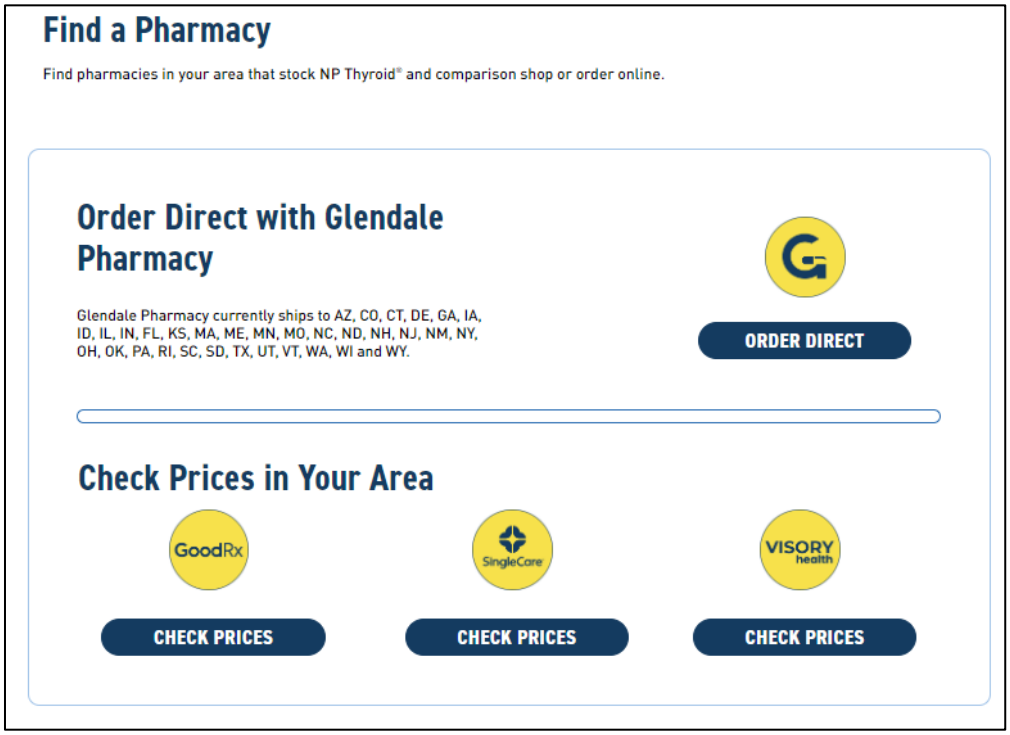
33. Acella also highlights its FDA-regulated and -inspected facilities on its promotional website to patients to reinforce the impression in patients' minds that Acella has FDA approval and has not and does not have any FDA inspection issues with respect to its manufacturing of NP Thyroid® Tablets. Exhibit 5, also available at https://npthyroid.com/for-patients/.



34. Upon information and belief, Acella continues to mislead its patients through its NP Thyroid® website by providing those patients with links to find doctors and pharmacies that falsely believe that NP Thyroid® Tablets are higher quality than other DTE tablets, including ANI's Thyroid Tablets, and falsely believe NP Thyroid® Tablets are an FDA authorized Generic or therapeutic equivalent to Armour® Thyroid. Id.



35. For example, by clicking through the find a pharmacy link on Acella's NP Thyroid® patient facing webpage the patient is led to a subsequent link to VISORY Health as shown below. Exhibit 6, also available at https://npthyroid.com/for-patients/find-a-pharmacy/.



36. Visory Health's website discloses that it is a company dedicated to providing "[b]etter prescription savings at the pharmacy." See https://www.visoryhealth.com/.

37. A search for Armour® Thyroid on Visory Health's webpage improperly promotes NP Thyroid® Tablets as "Generic Armour Thyroid". This false advertising of Acella's NP Thyroid® Tablets as Generic to Armour® Thyroid, not just an alternative pharmaceutically equivalent DTE product, misleads patients and the market as to the nature and quality of Acella's NP Thyroid® Tablets. Exhibit 7, also available at https://www.visoryhealth.com/search (Search for "Armour Thyroid" input).

38. Likewise, a search for NP Thyroid® on Visory Health falsely promotes NP Thyroid® as "Generic Armour Thyroid". Exhibit 8, also available at https://www.visoryhealth.com/search (Search for "NP Thyroid" input).

39. This explicit use of "Generic" to describe Acella's NP Thyroid® Tablets falsely and/or misleadingly encourages the belief that Acella's NP Thyroid® Tablets

are FDA approved, AB rated or therapeutically equivalent generics according to the following FDA definition:

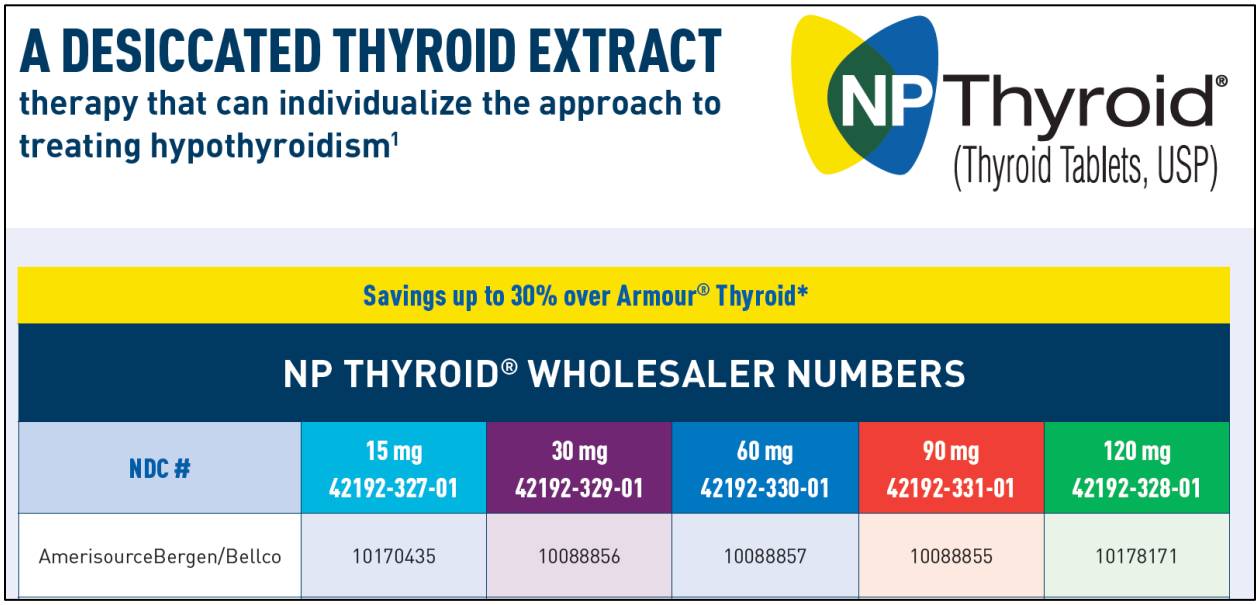
> **Generic Drug**
> A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#G.

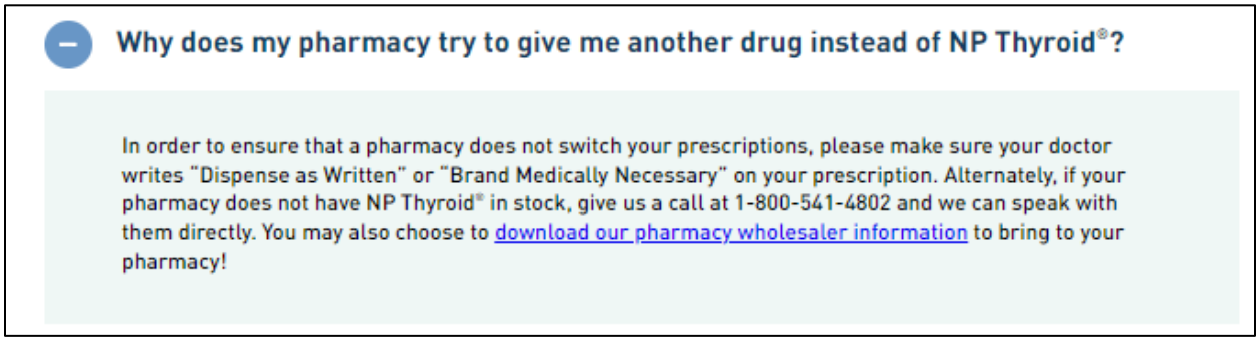
40. A significant portion of the healthcare industry, including wholesalers, pharmacies, insurers, healthcare providers, and individuals employed thereby utilize the FDA's definition of "Generic Drug" for prescription drug products marketed as generic.

41. Upon information and belief, based on Acella's false advertising, purchasers including wholesalers and pharmacies are more likely to purchase NP Thyroid® over ANI's Thyroid Tablets.

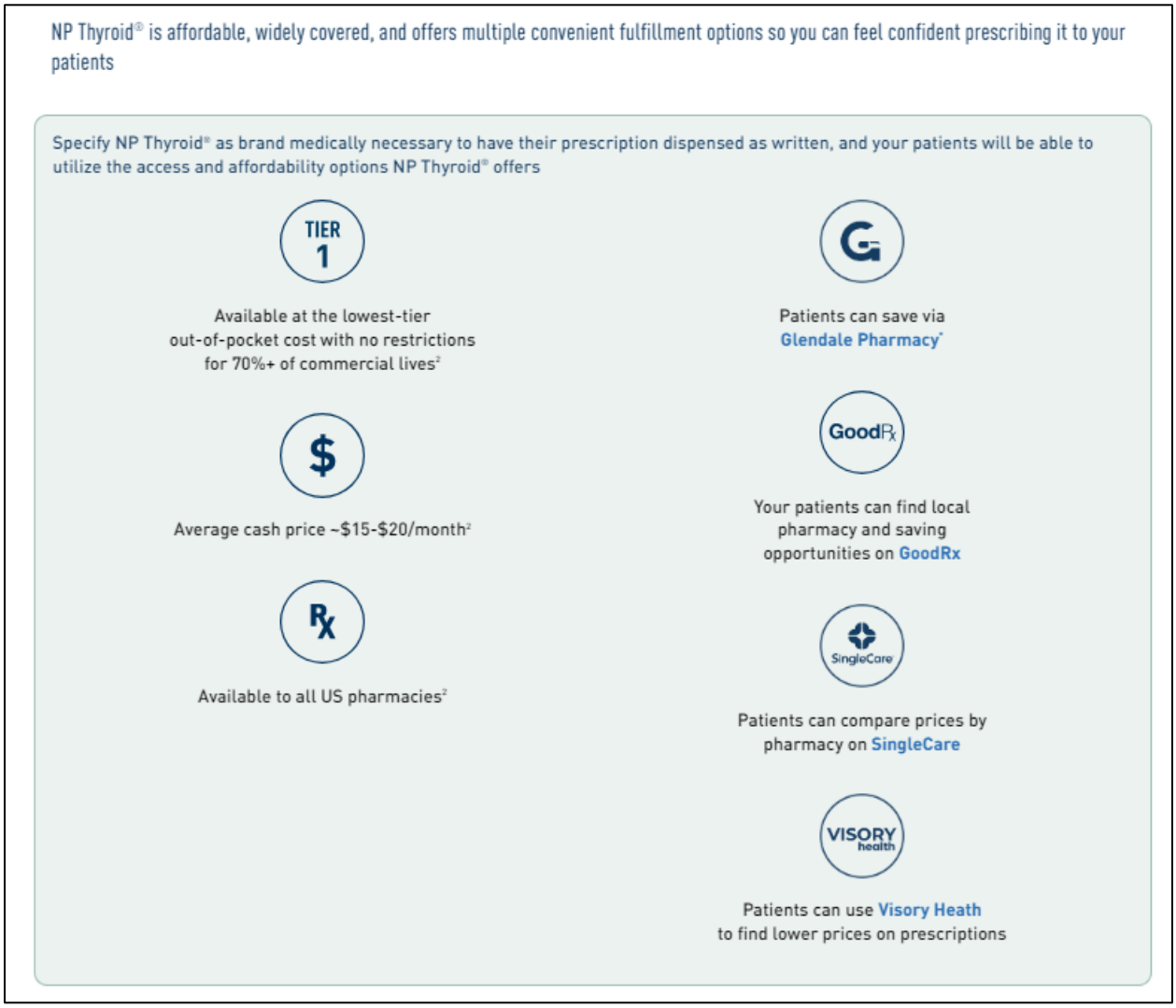
42. Acella advertises savings up to 30% over Armour® Thyroid. Exhibit 9 (Acella Wholesale Ordering PDF available through https://npthyroid.com/faq/.



43. Acella's systemic misrepresentation of the nature and quality of its products and the substitutability of Acella's product with respect to other DTE tablets continues on Acella's NP Thyroid® websites' webpage for "Frequently Asked Questions" ("FAQs"). Acella's FAQs webpage is designed to mislead DTE consumers and potential consumers into requesting their prescribers write "brand medically necessary" or "dispense as written" on their prescriptions, and that Acella's product is medically necessary over other DTE tablets, including ANI's Thyroid Tablets, without any medical basis. Acella tells patients that "[i]n order to ensure that a pharmacy does not switch your prescriptions, please make sure your doctor writes 'Dispense as Written' or 'Brand Medically Necessary' on your prescription." Exhibit 10, also available at https://npthyroid.com/faq/.



44. Acella continues to misrepresent its NP Thyroid® to prescribers so that they will write dispense as written or brand medically necessary for NP Thyroid® prescriptions. To do this, Acella promotes its NP Thyroid® as "affordable" and "widely covered" so prescribers will "feel confident prescribing it to their patients, and that the prescriber should be writing "brand medically necessary" or "dispense as written" on the prescriptions, not for medical reasons, but so that their "patients will be able to utilize the access and affordability options NP Thyroid® offers." Exhibit 11, also available at https://npthyroid.com/for-practitioners/.



This practice misleads prescribers into believing that writing "brand medically necessary" or "dispense as written" will enable the patient to access affordable, widely covered, NP Thyroid® when there are cheaper alternatives available such as ANI's Thyroid Tablets for the patient were the prescriber not to write "brand medically necessary" or "dispense as written".

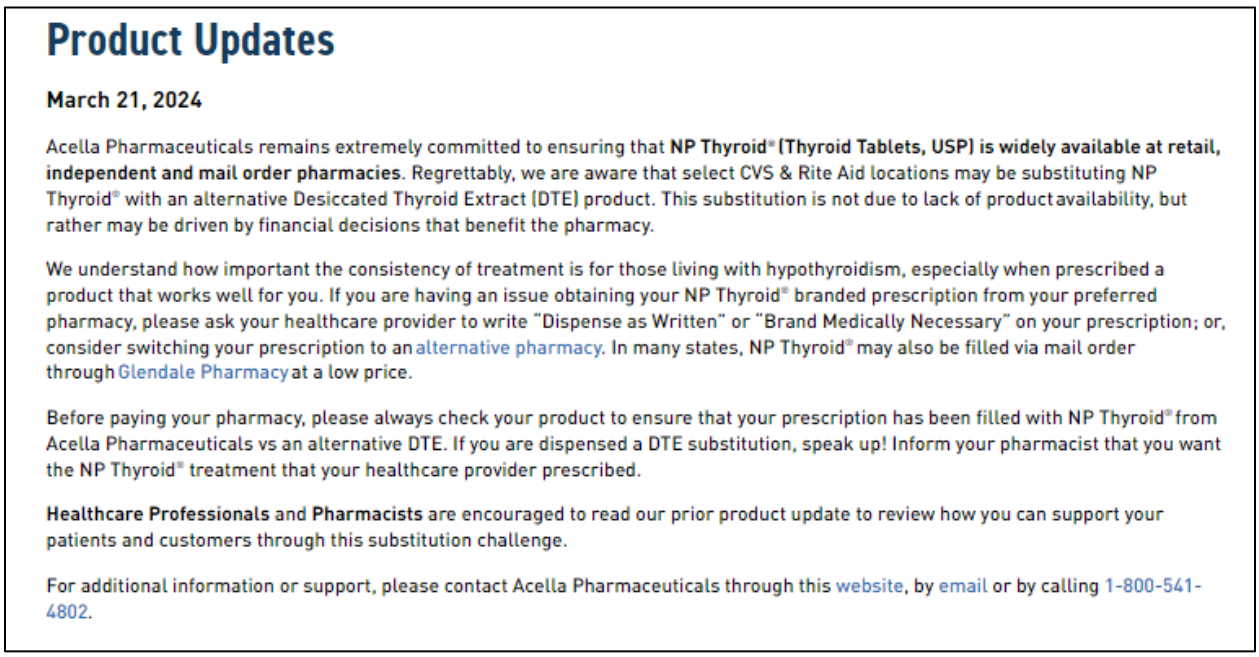
45. Upon information and belief, Acella's website also falsely advertises the insurance coverage and cash price for NP Thyroid®. As shown above, Acella aggressively markets its formulary coverage ("Available at the lowest-tier out-of-

pocket cost with no restrictions for 70%+ of commercial lives") and cost savings ("Average cash price ~$15-$20/month) as a reason prescribers should promote NP Thyroid® by writing prescriptions for NP Thyroid® as "brand medically necessary" or "dispense as written".

46. Upon information and belief, Acella does not have the lowest-tier out-of-pocket cost with no restrictions for 70%+ of commercial lives, nor is the average cash price of NP Thyroid® $15-$20/month. As shown above on the Visory Health search for NP Thyroid®, the monthly cost to fill a prescription of 30 tablets of 60mg NP Thyroid® Tablets is at least 47.5% greater than the NP Thyroid® webpage's advertised monthly cash price for NP Thyroid® Tablets. This practice impacts sales of ANI's Thyroid Tablets, which should be dispensed as a lower priced pharmaceutical equivalent to Armour® Thyroid or NP Thyroid® Tablets where appropriate.

47. Acella also directs prescribers to access and promote Visory Health ("Patients can use Visory Health to find lower prices on prescriptions") knowing that doctors who utilize that service will be misled as to the quality of Acella's NP Thyroid®, and falsely believe that NP Thyroid® is an FDA approved generic to Armour® Thyroid while other DTE tablets including ANI's pharmaceutically equivalent Thyroid Tablets are not generic to Armour® Thyroid and therefore of lower quality than Acella's NP Thyroid®, resulting in lost customers and sales for ANI's Thyroid Tablets and a loss of goodwill for ANI.

48. Upset that Acella was lawfully losing sales through price competition to ANI, Acella doubled down on its "dispense as written" / "brand medically necessary" campaign, specifically misleading the market into believing that product substitutions were occurring only for pharmacy benefit, not to lower patient and healthcare industry costs across the board through competitive price competition among manufacturers. Exhibit 12, also available at https://npthyroid.com/faq/product-updates/.



Product Updates

March 21, 2024

Acella Pharmaceuticals remains extremely committed to ensuring that **NP Thyroid® (Thyroid Tablets, USP) is widely available at retail, independent and mail order pharmacies**. Regrettably, we are aware that select CVS & Rite Aid locations may be substituting NP Thyroid® with an alternative Desiccated Thyroid Extract (DTE) product. This substitution is not due to lack of product availability, but rather may be driven by financial decisions that benefit the pharmacy.

We understand how important the consistency of treatment is for those living with hypothyroidism, especially when prescribed a product that works well for you. If you are having an issue obtaining your NP Thyroid® branded prescription from your preferred pharmacy, please ask your healthcare provider to write "Dispense as Written" or "Brand Medically Necessary" on your prescription; or, consider switching your prescription to an alternative pharmacy. In many states, NP Thyroid® may also be filled via mail order through Glendale Pharmacy at a low price.

Before paying your pharmacy, please always check your product to ensure that your prescription has been filled with NP Thyroid® from Acella Pharmaceuticals vs an alternative DTE. If you are dispensed a DTE substitution, speak up! Inform your pharmacist that you want the NP Thyroid® treatment that your healthcare provider prescribed.

Healthcare Professionals and **Pharmacists** are encouraged to read our prior product update to review how you can support your patients and customers through this substitution challenge.

For additional information or support, please contact Acella Pharmaceuticals through this website, by email or by calling 1-800-541-4802.

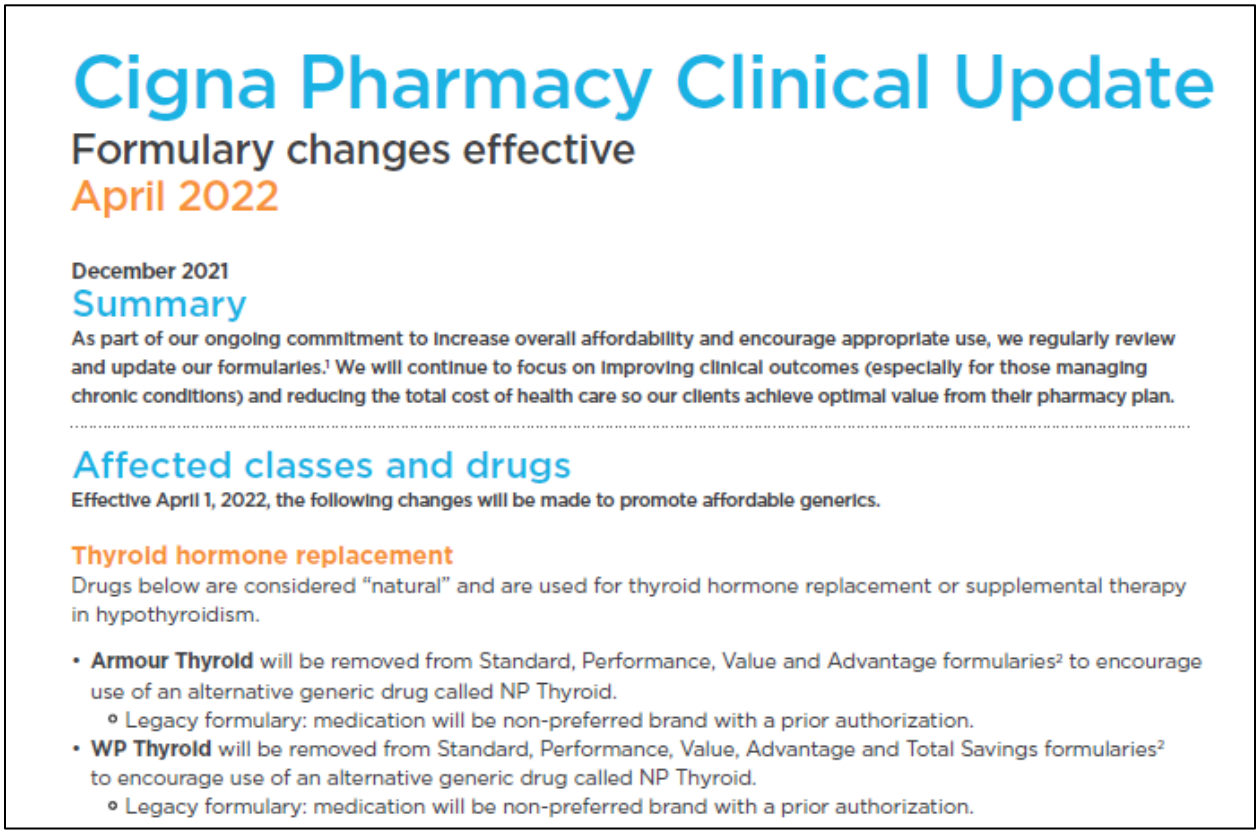
Acella's False Advertising Through Drug Formularies

49. Upon information and belief, to boost sales of NP Thyroid® over competitors like ANI, Acella markets NP Thyroid® as the generic DTE tablet for Armour® Thyroid to insurance entities and/or gives the misimpression that its NP Thyroid® Tablets are FDA approved, seeking favorable formulary placement despite comparable pricing with Armour® Thyroid. Consequently, NP Thyroid® attains generic tier status (Tier 1 or Tier 2) on formularies, while Armour® Thyroid is

relegated to lower-tier brand status (Tier 3 or Tier 4). This favorable positioning often requires pharmacists to make the substitution for insurance to cover the cost of the prescription and misleads pharmacists into assuming NP Thyroid® is therapeutically interchangeable with Armour® Thyroid while other DTE products are not, prompting substitution for NP Thyroid® without offering the patient and healthcare system the greatest cost savings. This practice impacts sales of ANI's Thyroid Tablets, which should be dispensed as a lower priced pharmaceutical equivalent where appropriate.

50. Upon information and belief, Acella's false advertising to drug formularies, directly and through its website, over its quality and the savings offered by its NP Thyroid® Tablets, has misled drug formularies and Pharmacy and Therapeutics ("P&T") Committees into believing NP Thyroid® is of higher quality than alternative DTE tablets, and is the generic to Armour® Thyroid. As a result of those formularies listings, Acella's NP Thyroid® Tablets are misperceived by healthcare participants who rely on those formularies to be of higher quality than other DTE tablets, FDA approved, and/or sanctioned by the FDA as generics that pharmacists should dispense for prescriptions written for Armour® Thyroid, before looking to alternative DTE products that offer additional cost savings.

51. Upon information and belief, Acella's strategy has been successful, and Acella has achieved top tier status in some formularies as a generic for Armour® Thyroid. This campaign has harmed ANI's entrance into the market, resulting in lost customers and sales for ANI's Thyroid Tablets. See Exhibit 13.



Cigna Pharmacy Clinical Update

Formulary changes effective April 2022

December 2021

Summary

As part of our ongoing commitment to increase overall affordability and encourage appropriate use, we regularly review and update our formularies.[1] We will continue to focus on improving clinical outcomes (especially for those managing chronic conditions) and reducing the total cost of health care so our clients achieve optimal value from their pharmacy plan.

Affected classes and drugs

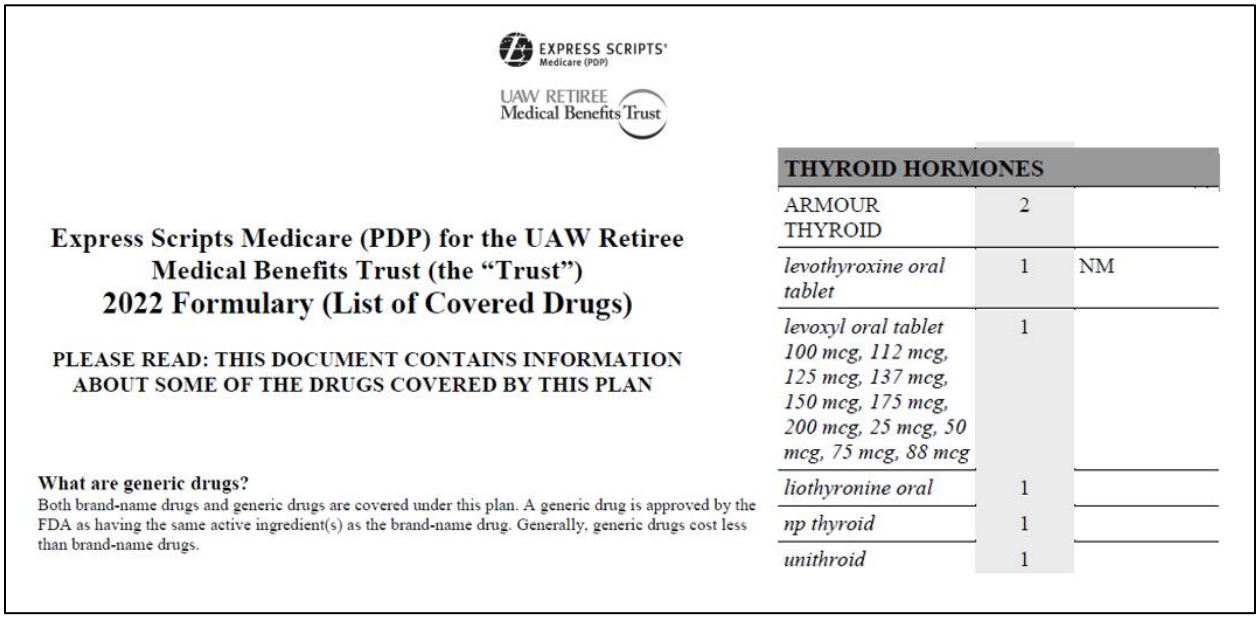
Effective April 1, 2022, the following changes will be made to promote affordable generics.

Thyroid hormone replacement

Drugs below are considered "natural" and are used for thyroid hormone replacement or supplemental therapy in hypothyroidism.

- **Armour Thyroid** will be removed from Standard, Performance, Value and Advantage formularies[2] to encourage use of an alternative generic drug called NP Thyroid.
  - Legacy formulary: medication will be non-preferred brand with a prior authorization.
- **WP Thyroid** will be removed from Standard, Performance, Value, Advantage and Total Savings formularies[2] to encourage use of an alternative generic drug called NP Thyroid.
  - Legacy formulary: medication will be non-preferred brand with a prior authorization.

52. Formularies covering patients are likewise being misled regarding the status of Acella's NP Thyroid® Tablets. For example, Acella falsely advertises its NP Thyroid® Tablets as FDA approved generics through the Express Scripts Formulary. The Express Scripts Formulary false and misleadingly describes NP Thyroid® as a generic drug that is "approved by the FDA as having the same active ingredient(s) as the brand-name drug." See Exhibit 14.



EXPRESS SCRIPTS Medicare (PDP)

UAW RETIREE Medical Benefits Trust

Express Scripts Medicare (PDP) for the UAW Retiree Medical Benefits Trust (the "Trust")
2022 Formulary (List of Covered Drugs)

PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT SOME OF THE DRUGS COVERED BY THIS PLAN

What are generic drugs?
Both brand-name drugs and generic drugs are covered under this plan. A generic drug is approved by the FDA as having the same active ingredient(s) as the brand-name drug. Generally, generic drugs cost less than brand-name drugs.

THYROID HORMONES		
ARMOUR THYROID	2	
levothyroxine oral tablet	1	NM
levoxyl oral tablet 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg	1	
liothyronine oral	1	
np thyroid	1	
unithroid	1	

53. Upon information and belief, drug products in lowercase italics are perceived to be FDA approved generic drug products in the Express Scripts formularies.

COUNT 1
(False Advertising)

54. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

55. ANI and Acella are direct head-to-head competitors for the sale of natural desiccated thyroid tablets.

56. Acella has used and, on information and belief, continues to use false and misleading descriptions and representations of fact in commercial advertising and promotion about the nature, characteristics, and qualities of its products and ANI's products so that retailers, wholesalers, pharmacies and patients will be misled into believing that ANI's Thyroid Tablets are an inferior or non-permissible substitute for

Acella's NP Thyroid® Tablets and/or that NP Thyroid® Tablets are the "generic" equivalent of Armour® Thyroid when ANI's Thyroid Tablets are an appropriate, lower-cost substitute for prescriptions written for DTE tablets. Those false and misleading descriptions and representations of fact have deceived or have the tendency to deceive a substantial portion of the relevant purchasing public.

57. Acella's false and misleading advertising includes a systemic campaign of marketing its NP Thyroid® Tablets as higher quality, medically necessary, and lower-cost products than alternative DTE tablets, including ANI's Thyroid Tablets.

58. As alleged above, Acella's advertising through its salesforce and its website includes numerous demonstrably false statements, misrepresentations, and misstatements of law, which interfere, and have interfered, with ANI's ability to sell its lower-cost pharmaceutically equivalent product and caused direct harm to ANI through loss of sales, customers and goodwill.

59. As alleged above, Acella's false advertising to prescribers, which contains numerous false statements, misrepresentations, and misstatements of law, has resulted in prescribers being misled into writing NP Thyroid® Tablets prescriptions as "Brand Medically Necessary" or "Dispense as Written" ("DAW") under the false premise that Acella's NP Thyroid® Tablets have top tier formulary coverage and will provide a cost savings to patients and the healthcare industry over other DTE tablets, including ANI's Thyroid Tablets.

60. These false and misleading statements by Acella constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

61. Acella causes, and has caused, its false and misleading advertising to enter interstate commerce, including by making false and misleading statements through its website, its advertising, and through drug formularies to consumers throughout the United States.

62. Acella's false and misleading statements are material in that they have and are likely to influence consumers' purchasing decisions and because they relate to inherent qualities or characteristics of Acella's products and ANI's products.

63. As a direct and proximate result of the wrongful acts of Acella alleged above, ANI has suffered, and will continue to suffer, substantial damage to its business reputation, goodwill, and market share, as well as loss of profits in an amount not yet ascertained.

64. Acella's false advertising will continue to harm ANI, causing irreparable injury for which there is no adequate remedy at law, unless permanently enjoined by this Court under 15 U.S.C. § 1116.

65. ANI is entitled to enhanced monetary damages of up to three times the amount of ANI's actual damages or Acella's profits resulting from Acella's false advertising, in an amount to be proven at trial, and the costs of the action under 15 U.S.C. § 1117(a).

66. ANI is also entitled to an accounting of Acella's profits resulting from its Lanham Act violations.

67. Upon information and belief, Acella's false advertising is willful, knowing, calculated to deceive, and was undertaken in bad faith. As a result, this Court should determine that this is an exceptional case and award ANI its attorneys' fees and costs incurred in prosecuting this action under 15 U.S.C. § 1117(a).

COUNT II
(Contributory False Advertising)

68. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

69. Upon information and belief, Acella is knowingly inducing or causing, and/or materially participating in, the false or misleading, or false and misleading, advertising and promotion of NP Thyroid® through drug formularies and third-party websites that list NP Thyroid® as the "generic" to Armour® Thyroid that must be dispensed according to the formularies provider before ANI's Thyroid Tablets may be dispensed.

70. Upon information and belief, Acella actively and materially furthered such false or misleading, or false and misleading, advertising and promotion of NP Thyroid® through the drug formularies, drug pricing databases, and third-party websites by making false or misleading, or false and misleading, representations about the products on Acella's NP Thyroid® website and directly to the drug formulary P&T

Committees and third-party websites that Acella's NP Thyroid® is the "generic" to Armour® Thyroid, and is of higher quality and lower-cost than alternative DTE tablets, including ANI's Thyroid Tablets. Based on this impression, the market is misled into believing that ANI's Thyroid Tablets are an inferior or non-permissible substitute for NP Thyroid® or Armour® Thyroid tablets.

71. Such false or misleading, or false and misleading, statements about NP Thyroid® by the drug formularies, drug pricing databases, and third-party websites have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of NP Thyroid® and ANI's Thyroid Tablets.

72. Such false or misleading, or false and misleading, statements about NP Thyroid® by the drug formularies, drug pricing databases, and third-party websites are material and likely to influence the purchasing decisions of wholesalers, third-party payors, pharmacists, health care professionals and others in the healthcare industry, as well as patients who consume ANI's and Acella's products.

73. These false or misleading, or false and misleading, representations were and are made in interstate commerce.

74. As a direct and proximate result of Acella's conduct, ANI has suffered damages, which includes a loss of sales, profits and customers, which ANI would have made but for the false and deceptive representations by Acella.

75. Acella's actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to ANI's business, reputation, and goodwill, unless Acella's unlawful conduct is enjoined by this Court.

76. Pursuant to 15 U.S.C. § 1116, ANI is entitled to preliminary and permanent injunctive relief to Acella's continuing acts.

77. Pursuant to 15 U.S.C. § 1117, ANI is entitled to recover all damages sustained by Acella's actions, an accounting for profits realized by Acella, and the costs of this action.

78. Acella's actions have been willful and deliberate, entitling ANI to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), ANI is entitled to an award of reasonable attorneys' fees.

COUNT III
(Common Law Unfair Competition)

79. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

80. Acella began a campaign in the mid to late 2010s to perpetuate demonstrably false statements, misrepresentations, and misstatements of law about Acella and its NP Thyroid® Tablets.

81. Acella's wrongful and intentional conduct included a systemic campaign of marketing its NP Thyroid® Tablets as a higher quality, medically necessary and

lower-cost product than alternative DTE tablets, including by misleading purchasers and those in the pharmaceutical supply chain into believing that NP Thyroid® is the "generic" of Armour® Thyroid, and that ANI's Thyroid Tablets are an inferior or non-permissible substitute for NP Thyroid® Tablets.

82. Acella's wrongful and intentional conduct unfairly hampered ANI's efforts to market, promote, and sell its Thyroid Tablets to both existing and potential customers.

83. Acella's wrongful and intentional conduct is not privileged and is actionable under Minnesota law.

84. Acella's wrongful and intentional conduct has caused damage to ANI in the form of lost sales, lost profits, and lost customers.

COUNT IV
(Violation of the Minnesota Unfair Trade Practices Act, Minn. Stat. § 325D.13)

85. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

86. Minn. Stat. § 325D.13 provides that:

87. "No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

88. 48. Minn. Stat. §§ 8.31, subd. 3a, and 325D.15 provide a private right of action to enforce the provisions of Minn. Stat. § 325D.13.

89. Acella has knowingly misrepresented the true quality and characteristics of Acella's NP Thyroid® Tablets, including by misleading purchasers and those in the pharmaceutical supply chain that NP Thyroid® is the "generic" of Armour® Thyroid, and is a higher quality, medically necessary and lower-cost product than ANI's Thyroid Tablets, misleading the market to believe that ANI's Thyroid Tablets are not a permissible substitute for NP Thyroid® Tablets.

90. Acella's false and misleading representations of fact and conduct have deceived or misled, or have a tendency to deceive or mislead, a substantial and appreciable segment of consumers and purchasers.

91. Upon information and belief, Acella's false and misleading representation of fact and conduct have influenced purchasing, stocking, substitution, and dispensing decisions or are likely to influence purchasing, stocking, substitution, and dispensing decisions for ANI's Thyroid Tablets and Acella's NP Thyroid®.

92. By reason of ANI's false and misleading representations of fact and conduct, ANI has suffered and will continue to suffer damage to its business, reputation and goodwill.

93. Pursuant to Minn. Stat. §§ 8.31 and 325D.15, ANI is entitled to enjoin Acella's unlawful conduct as well as recover damages, costs and disbursements, and reasonable attorneys' fees.

COUNT V
(Violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.44)

94. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

95. Minn. Stat. § 325D.44, subd. 1, provides that:

96. A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person . . . .

> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another; . . .
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have; . . .
> (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> . . .
> (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;

97. Minn. Stat. § 325D.45 provides a private right of action to enforce the provisions of Minn. Stat. § 325D.44.

98. In the course of its business, Acella has engaged in and continues to engage in deceptive trade practices in violation of Minnesota Statute section 325D.44, by and through its false and misleading representations of fact and conduct concerning the true quality and characteristics of Acella's NP Thyroid® Tablets, including by misleading purchasers and those in the pharmaceutical supply chain that NP Thyroid®

is the "generic" to Armour Thyroid and that ANI's Thyroid Tablets are an inferior or non-permissible substitute for NP Thyroid® because it is a higher quality and lower-cost product than alternative DTE tablets, including ANI's Thyroid Tablets.

99. Acella has willfully engaged in its actions regarding its NP Thyroid® Tablets, knowing them to be deceptive.

100. By reason of Acella's conduct, ANI has suffered and will continue to suffer damage to its business, reputation, and goodwill.

101. Pursuant to Minn. Stat. § 325D.45, ANI is entitled to enjoin Acella's unlawful conduct as well as recover costs and reasonable attorneys' fees.

COUNT VI
(Violation of the Minnesota False Advertising Act, Minn. Stat. § 325F.67)

102. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

103. Minn. Stat. § 325F.67 provides that:

> Any person … who, with intent to sell … merchandise, … makes, publishes, disseminates, circulates, or places before the public, … in this state, in a newspaper or other publication, or in the form of a book, notice, handbill, poster, bill, label, price tag, circular, pamphlet, program, or letter, or over any radio or television station, or in any other way, an advertisement of any sort regarding merchandise, … which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

104. Minn. Stat. § 8.31, subd. 3a provides a private right of action to enforce the provisions of Minn. Stat. § 325F.67.

105. Through advertising, Acella has intentionally and willfully made, published, disseminated, circulated, and placed before the public advertisements containing false, deceptive, and misleading statements about Acella's NP Thyroid® Tablets in the context of commercial advertising in the State of Minnesota and elsewhere, including that NP Thyroid® is the "generic" to Armour Thyroid and that ANI's Thyroid Tablets are an inferior or non-permissible substitute for NP Thyroid® because they are a higher quality and lower-cost product than alternative DTE tablets, including ANI's Thyroid Tablets.

106. By reason of Acella's conduct, ANI has suffered and will continue to suffer damage to its business, reputation and goodwill.

107. Pursuant to Minn. Stat. § 8.31, subd. 3a, Acella is entitled to enjoin ANI's unlawful conduct as well as damages, costs and disbursements, and reasonable attorneys' fees.

COUNT VII
(Violation of the Georgia Uniform Deceptive Trade Practices Act)

108. ANI re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully stated herein.

109. The Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372(a)(8), provides that "[a] person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he . . . [d]isparages the goods, services, or business of another by false or misleading representation of fact."

110. In the course of its business, Acella has engaged in and continues to engage in deceptive trade practices in violation of the Georgia Uniform Deceptive Trade Practices Act, by and through its false and misleading representations of fact and conduct concerning the true quality and characteristics of ANI's Thyroid Tablets and Acella's NP Thyroid® Tablets, including by misleading purchasers and those in the pharmaceutical supply chain that NP Thyroid® is the "generic" to Armour Thyroid and that ANI's Thyroid Tablets are not a permissible substitute for NP Thyroid® because it is a higher quality and lower-cost product than alternative DTE tablets, including ANI's Thyroid Tablets.

111. Acella's wrongful, knowing, and intentional deceptive conduct is not privileged and is actionable under Georgia law.

112. By reason of Acella's wrongful and intentional conduct, ANI has suffered and will continue to suffer damage to its business, reputation, and goodwill.

JURY DEMAND

ANI demands a trial by jury.

PRAYER FOR RELIEF

Wherefore, ANI respectfully requests that the Court enter judgment for ANI and against Acella and grant the following relief:

(a) An order permanently enjoining Acella from using false and misleading descriptions and representations of fact in commercial advertising and promotion about the nature, characteristics, and qualities of its products;

(b) Compensatory damages in an amount to be proven at trial;

(c) Punitive damages;

(d) A declaration that Acella is not entitled to damages, interests, costs, or any other relief associated with this action;

(e) A declaration that this case is exceptional and ANI is entitled to an award of reasonable attorney fees and costs under 15 U.S.C. § 1117(a); and

(f) Any other relief this Court deems just and proper.

Respectfully submitted this 16th day of April, 2024.

FISHER BREN & SHERIDAN, LLP

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